DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 12, 2014

Lang Dental Manufacturing Co., Inc.
c/o Michelle Schlitz-Taing
Regulatory Affairs Product Registration Manager
Bisco, Inc.
1100 West Irving Park Road
Schaumburg, IL 60193

Re: K141439
Trade/Device Name: Orthodontic Acrylic
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture Relining, Repairing, or Rebasing Resin
Regulatory Class: II
Product Codes: EBI
Dated: June 24, 2014
Received: June 26, 2014

Dear Ms. Schlitz-Taing:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
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Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
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Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) Number (if known): K141439

Device Name: Orthodontic Acrylic

Orthodontic Acrylic is intended for the fabrication of methacrylate-based orthodontic appliances (such as retainers, bite guards, and bite plates, etc.)

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510 (k) SUMMARY

Applicant:	Lang Dental Manufacturing Company Incorporated 175 Messner Drive P.O. Box 969 Wheeling, Illinois 60090-0969
Contact Person:	Michelle Schiltz-Taing Tel: 847-534-6146 Fax: 847-534-6146
Date Prepared:	22 May 2014
Trade Name:	Orthodontic Acrylic
Common Name:	Fast Curing Orthodontic Acrylic Resin Powder and Liquid
Product Code:	EBI
Classification/Name:	Denture relining, repairing, or rebasing resin **Class II per 21 CFR 872.3760**

Predicate Devices:

Orthodontic Acrylic is substantially equivalent to the following Lang Dental Manufacturing Company Incorporated's:

Ortho-Jet Acrylic Resin – Sparkle (K941925)
and Ortho-Jet (a pre-amendment device in continuous distribution since 1969)

Indications for Use:

Orthodontic Acrylic intended for the fabrication of methacrylate-based orthodontic appliances (such as retainers, bite guards, and bite plates, etc.).

Description of Applicant Device:

Orthodontic Acrylic is a fast curing self-cure 2-part system. The system consists of a powder and a liquid. The combination of the powder and liquid is converted into a hard methacrylate finished product.

Technological Characteristics:

Orthodontic Acrylic is based upon industry standard chemistry. The Orthodontic Acrylic Liquid contains Quaternary Ammonium Methacryloxy Silicate (QAMS). In-vitro testing on *Candida albicans*, *Streptococcus mutans* and *Actinomyces naselundii* was conducted. In-vivo clinical studies to evaluate the effect of QAMS in the oral

environment and the prevention of bacteria and fungus-induced stomatitis have not been performed.

Comparisons of the chemical composition of Orthodontic Acrylic to the predicate are provided in the following table:

Chemical Composition	Ortho-Jet Acrylic Resin - Sparkle K941925	Orthodontic Acrylic
Auto-Polymerizing	X	X
Methacrylate Resin	X	X
Plasticized poly-methyl methacrylate	X	X
3:1 (Powder: Liquid) ratio	X	X
Quaternary Ammonium Methacryloxy Silicate (QAMS)	---	X

Performance Data:

The physical/mechanical properties of Orthodontic Acrylic were tested in the lab using ISO 20795-2:2010 for flexural strength, flexural modulus, fracture toughness, water sorption, and water solubility. The information provided in this 510(k) for Orthodontic Acrylic compared to the predicate demonstrates that they are similar.

In-vitro testing was conducted on *Candida albicans*, *Streptococcus mutans* and *Actinomyces naselundii*.

Biocompatibility:

An evaluation of biocompatibility was conducted using ISO 7405:2008 and ISO 10993-1 to testing requirements to determine the safety of Orthodontic Acrylic.

Orthodontic Acrylic was tested for Guinea Pig Maximization Sensitization Testing and Oral Mucosal Irritation (ISO 10993-10) and cytotoxicity (ISO 10993-5); Orthodontic Acrylic met the requirements for these tests.

Conclusion:

Side by side comparisons demonstrate that the applicant device is substantially equivalent to the predicate legally marketed devices.